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Supreme Court, U.S.
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No. 95-2018

IN THE

Supreme Court of the United States

October Term, 1995

HOWMEDICA INC.,

Petitioner,

v.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

REPLY BRIEF FOR PETITIONER

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Petitioner Howmedica Inc. ("Howmedica") hereby submits this reply brief in response to Respondent's Brief in Opposition. As pointed out in Petitioner's previously filed Supplemental Brief in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625 (U.S. June 26, 1996), the Petition presents a question that was not resolved by the Court's decision in *Medtronic*: whether the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360 *et seq.* (1994), pre-empt a state-law action directed at a medical device that has actually passed the Food & Drug Administration's ("FDA") scrutiny.

ARGUMENT

Respondent attempts to divert the Court's attention from the question presented by suggesting that there are factual issues rendering this case unsuitable for review. Although Petitioner disagrees with Respondent's assertions as to the record below, none of Respondent's contentions goes to the certworthiness of the Petition save one: the claim that the device at issue, known as the P.C.A.® Total Knee System, was a Class II device marketed pursuant to the § 510(k) process, Respondent's Brief in Opposition at 3, rather than a device authorized for use as an experimental device in a clinical investigation pursuant to the FDA's Investigational Device Exemption ("IDE") process. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a); 21 C.F.R. Pt. 812 (1995).

The regulatory history of this particular device is set forth in detail in *Dawson v. Howmedica, Inc.*, 886 F. Supp. 1402, 1406-07 (E. D. Tenn. 1995). The FDA granted Petitioner's IDE application in 1982, and the device that was implanted in plaintiff in 1985 was utilized during the period in which the IDE clinical investigation was underway. *Id.* at 1406. At a later date, the FDA granted premarket approval. 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). As a result, Respondent's claim that the device is unreasonably dangerous by reason of design defects directly attacks the FDA's reasoned judgment to permit the device to be investigated under the IDE process, and thereafter marketed generally after having undergone the exhaustive PMA process.

This case therefore presents a significant issue that has not been resolved by *Medtronic* regarding the nature and scope of pre-emption for Class III devices that have been fully reviewed and approved by the FDA under the IDE/PMA process, and the subject matter jurisdiction of state courts over such claims generally.

CONCLUSION

For all the foregoing reasons, this Court should grant certiorari in this case and reverse the holding of the Illinois Supreme Court. At a minimum, this Court should vacate and remand this case for consideration in light of *Medtronic*.

Respectfully submitted,

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Dated: August 6, 1996